PULSE OXIMETER (FOX-BABY)
User Manual
Nomer File: SPA-BM/PROD-45
Revisi: 04
Release Date : 26 March 2025

User Notice

Dear users, thank you very much for purchasing the Pulse Oximeter (herein after referred to as device).
It is a medical device, which can be used repeatedly.
The manual describes, in accordance with the device's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as safety procedures to protect both the users and equipment. Refer to the respective chapter for details.
Please read the user manual very carefully before using this device. The user manual which describes the operating procedures should be followed strictly. Failure to follow the user manual may cause measuring abnormality, device damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and device damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.
Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

Warnings

Remind that it may cause serious consequences to tester, user or environment.

- Explosive hazard - DO NOT use the device in environment with inflammable gas such as anesthetic.
- DO NOT use the device while examining by MRI or CT, as the induced current may cause burn.
- Do not take the information displayed on the device as the sole basis for clinical diagnosis. The device is only used as an auxiliary means in diagnosis. And it must be used in conjunction with doctor's advice, clinical manifestations and symptoms.
- The maintenance to the device non-detachable lithium battery can only be performed by qualified service personnel specified by manufacturer, dangers (such as over-temperature, fire, or explosion) may occur when replacing the battery by the personnel not fully trained. Users are not permitted to maintain or refit the device by themselves or replacement of the battery.
- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation disturbance users. It is not recommended that the sensor is used on the same finger for more than 2 hours.
- For some special users who need a more careful inspection on the test site, please don't place the device on the edema or tender tissue.
- Please do not stare at the red and infrared light emitter (the infrared light is invisible) after turning on the device, including the maintenance staff, as it may be harmful to the eyes.
- The device contains silicone, PVC, TPU, TPE, and ABS materials, whose biocompatibility has been tested in accordance with the requirements in ISO 10993-1, and it has passed the recommended biocompatibility test. The person who is allergic to silicone, PVC, TPU, TPE, or ABS cannot use the device.
- DO NOT strand the lanyard to avoid device drop and damage. The lanyard is made of insensitive material. Please do not use it if any person is allergic to lanyard. Do not wrap the lanyard around neck to avoid an accident.
- The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.
- The device cannot be used with the equipment not specified in the manual. Only the accessories appointed or recommended by the manufacturer can be used, otherwise it may cause injury to the tester and operator or damage to the device.
- Check the device before use to make sure that there is no visible damage that may affect user's safety and device performance. When there is obvious damage, please replace the damage parts before use.
- Functional testers cannot be used to assess the accuracy of the Pulse Oximeter.
- Some functional testers or patient simulators can be used to verify whether the device works normally, for example, INDEX-2LFE Simulator (software version: 3.00), please refer to the manual for the detailed operation steps.
- Some functional testers or patient simulators can measure the accuracy of the device copied calibration curve, but they cannot be used to evaluate the device accuracy.
- When using the device, please keep it away from the equipment which can generate strong electric field or strong magnetic field. Using the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- When storing the device, keep it away from children, pets, and insects to avoid affecting its performance.
- Do not place the device in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool, or easy to splash water, to avoid affecting its performance.
- The measured accuracy will be affected by the interference of electrosurgical equipment.
- When several products are used on the same patient simultaneously, danger may occur which is arisen from the overlap of leakage current.
- CO poisoning will appear excessive estimation, so it is not recommended to use the device.
- This device is not intended for treatment.
- The intended operator of the device may be a patient.
- Avoid maintaining the device during using.

1. Overview

The oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood, it is an important physiological parameter for the respiratory and circulatory system. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patient's SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

Insert the finger when measuring, the device will directly display the SpO_2 value measured, it has a higher accuracy and repeatability.

1.1 Features

A. Easy to use.
B. Small in volume, light in weight, convenient to carry.
C. Low power consumption.

1.2 Indication for Use

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger. The product is fit for family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports and it is not recommended to use the device during the process of having sport) and etc.

1.3 Environment requirements

Storage Environment
a) Temperature: -40°C ~ +60°C
b) Relative humidity: ≤95%
c) Atmospheric pressure: 500 hPa ~ 1060 hPa
Operating Environment
a) Temperature: +10°C ~ +40°C
b) Relative Humidity: ≤75%
c) Atmospheric pressure: 700 hPa ~ 1060 hPa

1.4 Precautions

1.4.1 Attention

Point out conditions or practices that may cause damage to the device or other properties.

- Before using the device, make sure that it locates in normal working state and operating environment.
- In order to get a more accurate measurement, it should be used in a quiet and comfortable environment.
- When the device is carried from cold environment to warm or humid environment, please do not use it immediately, wait four hours at least is recommended.
- If the device is splashed or coagulated by water, please stop operating
- DO NOT operate the device with sharp things.
- High temperature, high pressure, gas sterilizing, or immersion disinfection for the device is not permitted. Refer to user manual in the relative chapter (6.1) for cleaning and disinfection. Please turn off the device before cleaning and disinfection.
- The device is suitable for children.
- The device may not be suitable for all users, if you can't get a satisfactory result, please stop using it.
- Data averaging and signal processing have a delay in the upgrade of SpO_2 data values. When the data update period is less than 30 seconds, the time for obtaining dynamic average values will increase, which is arisen from signal degradation, low perfusion or other interference, it depends on the PR value.
- The device has 3 years' service life, date of manufacture: see the label
- The maximum temperature at the SpO_2 probe – tissue interface should be less than 41°C which is measured by the temperature tester.
- During measuring, when abnormal conditions appear on the screen, please pull out your finger and reinsert it to measure again.
- Do not contort or drag the wire of the device.
- The plethysmography waveform is not normalized, as a signal inadequacy indicator, when it is not smooth and stable, the accuracy of the measured value may degrade. When it tends to be smooth and stable, the measured value read is the optimal and the waveform at this time is also the most standard.
- The device cannot be used during charging
- If the device or component is intended for single-use, then the repeated use of these parts will pose risks on the parameters and technical parameters of the equipment known to the manufacturer.
- If necessary, our company can provide some information (such as circuit diagrams, component lists, illustrations, etc.), so that the qualified technical personnel of the user can repair the device components designated by our company.
- The measured results will be influenced by the external coloring agent (such as nail polish, coloring agent or color skin care products, etc.), so don't use them on the test site.
- As to the fingers which are too cold or too thin or whose fingernail is too long, it may affect the measured results, so please insert the thicker fingers such as thumb or middle finger deeply enough into the probe when measuring.
- The finger should be placed correctly (see attached figure 3), as improper installation or improper contact position for sensor will influence the measurement.
- The light between the photoelectric receiving tube and the light-emitting tube of the device must past through the subject's arteriole. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate results.
- Excessive ambient light may affect the measured results, such as surgical light (especially xenon light sources), bilirubin lamp, fluorescent lamp, infrared heater, and direct sunlight, etc. In order to prevent interface from ambient light, make sure to place the sensor properly and cover the sensor with opaque material.
- Frequent movement (active or passive) of the subject or severe activity can affect the measured accuracy.
- The SpO_2 probe should not be placed on a limb with the blood pressure cuff, arterial ductus or intraluminal tube.
- The measured value may be inaccurate during defibrillation and in a short period after defibrillation, as it has not defibrillation function.
- The device has been calibrated before leaving factory.
- The device is calibrated to display functional oxygen saturation.
- The equipment connected with the oximeter interface should comply with the requirements of IEC 60601-1.
- Please select medical power adapter to charge it, when connecting the special adapter with the socket, make sure there is no shelter near the socket and it is easy to plug and unplug, otherwise the power will not be cut off in time when necessary, causes damage.

1.4.2 Clinical Restriction

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/ body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
B. The measurement will be influenced by intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.
C. The measured value may be normal seemingly for the tester who has anemia or dysfunctional hemoglobin (such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb), and sulfhaemoglobin (SuHb)), but the tester

may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.

D. Pulse oxygen only has a reference meaning for anemia and toxic hypoxia, as some severe anemia patients still show better pulse oxygen measured value.

E. Contraindication: No.

2. Principle

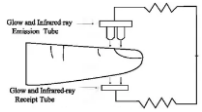

Figure 1 Operating principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

3. Functions

A. SpO_2 value display

B. PR value and bar graph display

C. Pulse waveform display

D. Low-battery indication: low-battery indication appears when the battery voltage is too low to work

E. Automatic standby function

F. Display mode can be changed

G. Charging function

H. Display direction can be changed automatically

I. PR sound indication: sound prompt for over-limit, low battery

4. Installation

4.1 Appearance

Figure 2 Appearance and Measurement Interface

USB interface: connect with USB cable

Button: power on, pause sound prompt

4.2 Connection of USB cable

Insert the micro end of the USB cable into the device, the other end into computer or power adapter.

4.3 Structure, accessories, and software description

A. Structure: main unit, USB cable, power adapter (optional).

B. Accessories: one USB cable, one power adapter (optional), one user manual, one lanyard.

Please check the device and accessories according to the list to avoid that the device cannot work normally.

C. Software description

Release version: V2.0

5. Operating

6.1 Measurement

A. Insert the finger into the probe as shown in Figure 3.

Figure 3 Sketch map for finger placement

B. Wait a few seconds, the device directly shows measurement result on the screen.

Note: when inserting the finger, the light emitting from the sensor must be directly irradiated to the side of the fingernail.

Note: during measuring, do not shake the finger and keep quiet, not move.

6.2 Pulse Sound Setting

After turning the device on, the pulse sound is open. Long press the button can close the pulse sound and the pulse sound indication icon disappears. Long press button again, the pulse sound is turned on and pulse sound indication appears.

6.3 Sound prompt setting

a. Sound prompt includes the sound prompt of measure data's going beyond the limits (when the SpO_2 is below 90%, or the pulse rate is not between 50 bpm and 120 bpm, the sound prompt occurs), the sound prompts of low-power.

b. In the open state of sound prompt, when the measure data is beyond the normal measure range, the device would give prompt sound and the corresponding value glitter. Sound prompt could be suspended by short pressing button, and the sound prompt icon disappears, but the value still glitter. Sound prompt function will be renewed in 30 seconds.

⚠ If low-power sound prompt occurs, please charge the battery.

6.4 Charging

Power adapter can be selected to charge for the device. It indicates that the device is charging when the indicator is light, the charging is finished when the indicator is off.

6. Maintain, Transport, and Storage

6.1 Cleaning and Disinfection

The device must be turned off before cleaning, and it should not be immersed into liquid.

Use 75% alcohol to wipe the device enclosure, and use liquid soap or isopropanol to wipe the watchband for disinfection, nature dry or clean it with clean and soft cloth. Do not spray any liquid on the device directly, and avoid liquid penetrating into the device.

6.2 Maintenance

A. Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.

B. Please clean and disinfect the device before/ after using it according to the user manual (6.1)

C. Please charge the battery in time when low battery appears.

D. Recharge the battery soon after over-discharge. The device should be recharged every three months when it is not used for some time. It can extend the battery life following this guidance.

E. The device need not to be calibrated during maintenance.

6.3 Transport and Storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and splashing with rain or snow, and it cannot be transported mixed with toxic, harmful, corrosive materials.

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C~+60°C; Relative Humidity: ≤95%.

7. Troubleshooting

Trouble	Possible Reason	Solution
The values cannot be displayed normally or stably.	1. The finger is not properly inserted. 2. The finger is shaking or the patient is moving. 3. The device is not used in environment required by the manual. 4. The device works abnormally.	1. Please insert the finger properly and measure again. 2. Let the patient keep calm. 3. Please use the device in normal environment. 4. Please contact the after sales.
The device cannot be turned on.	1. The battery is drained away or almost drained away. 2. The battery is installed incorrectly. 3. The device's malfunction	1. Please charge batteries. 2. Please install the battery again. 3. Please contact the local service center.
The display disappears suddenly.	1. The device enters into the energy saving mode. 2. Low battery. 3. The device works abnormally.	1. Normal. 2. Please charge the battery. 3. Please contact the after-sales.
The device cannot be used for full time after charge.	1. The battery is not charged fully. 2. The device works abnormally.	1. Please charge the battery. 2. Please contact the after-sales.
The battery cannot be fully charged even after 10-hour charging time.	The device works abnormally.	Please contact the after sales.

8. Symbols

Symbols	Meaning	Symbols	Meaning
	Caution, consult accompanying documents	PRbpm	Pulse rate (bpm)
	Type BF applied part	%SpO_2	Pulse oxygen saturation (%)
- - -	1. The finger clip falls off (no finger inserted) 2. Probe error 3. Signal inadequacy indicator		Low-power indication
SN	Serial Number		Use-by date
	Recycling garbage WEEE (2002/96/EC)		USB
	The sound prompt indication		The pulse sound indication
IP22	International Protection	Finger Out	The finger is not inserted
	Temperature limitation		Fragile, handle with care
	Atmospheric pressure limitation		This way up
	Humidity limitation		Keep away from rain
	Recyclable		Manufacture date
	Alarm inhibit		

Note: Your device may not contain all the following symbols.

9. Specification

SpO_2 [see note 1]	
Display range	0% ~ 99%
Measured range	0% ~ 99%
Accuracy [see note 2]	70% ~ 99%: ±2%; 0% ~ 70%: unspecified.
Resolution	1%
PR	
Display range	30 bpm ~ 249 bpm
Measured range	30 bpm ~ 249 bpm
Accuracy	±2bpm or ±2%, whichever is greater
Resolution	1 bpm
Accuracy under low perfusion [see note 3]	Low perfusion 0.4%: SpO_2: ±4%, PR: ±2 bpm or ±2%, whichever is greater
Light interference	Under normal and ambient light conditions, the SpO_2 deviation ≤1%
Pulse intensity	Continuous bar graph display, the higher display indicates the stronger pulse.
Upper and lower limit of measured values	
SpO_2	0% ~ 99%
PR	30 bpm ~ 249 bpm
Optical sensor [see note 4]	
Red light	Wavelength: about 660 nm

	Optical output power: <6.65 mW
Infrared light	Wavelength: about 905 nm Optical output power: <6.75 mW
Safety class	Internally powered equipment, type BP applied part
International protection	IP22
Working voltage	DC 3.6V ~ 4.2V
Working current	≤ 80 mA
Power supply	A rechargeable lithium battery (3.7 V) (The red wire on the battery denotes anode, the black wire on the battery denotes cathode).
Battery life	Charge and discharge: no less than 500 times.
Adapter specification	Output voltage: DC 5V Output current: 1000 mA
Dimension and Weight	
Dimension	46(L) x 40(W) x 29(H) mm
Weight	About 35 g (including a lithium battery)
Display	
Display Size	1.25inch

Appendix 1

State	Sound prompt condition delay	Sound prompt signal generation delay
Low voltage sound prompt	1s	20ms
SpO_2 sound prompt	330ms	20ms
Pulse rate sound prompt	330ms	20ms
Probe error sound prompt	16ms	20ms